

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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LESLIE COSOLITO, on behalf of
A.C., her minor child,

**COMPLAINT AND
JURY DEMAND**

Plaintiffs,

-against-

Index No.:

GLAXOSMITHKLINE, LLC

Defendant.

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COMPLAINT AND JURY DEMAND

Plaintiff, LESLIE COSOLITO, on behalf of her daughter A.C., a minor, ("Plaintiffs"), who by and through the undersigned counsel hereby submit this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline (hereinafter, "GSK" or "Defendant") for compensatory and punitive damages, and such other relief deemed just and proper arising from the injuries to A.C. as a result of her prenatal exposures to the generic bioequivalent form of the prescription drug Zofran®, also known as ondansetron. In support of this Complaint, Plaintiffs allege the following:

INTRODUCTION

1. Zofran is a powerful drug developed by GSK to treat only those patients who were afflicted with the most severe nausea imaginable - that suffered as a result of chemotherapy or radiation treatments in cancer patients.

2. The U.S. Food and Drug Administration ("FDA") approved Zofran in 1991 for use in cancer patients who required chemotherapy or radiation therapy.

3. Although the only FDA approval for this drug was for seriously ill patients, GSK marketed Zofran "off label" as a safe and effective treatment for the very common side effect of a normal pregnancy - pregnancy-related nausea and vomiting - otherwise known as "morning sickness." GSK further marketed Zofran during this time as a "wonder drug" for pregnant women, despite having knowledge that GSK had never once undertaken a single study establishing that this powerful drug was safe or effective for pregnant mothers and their growing children *in utero*. Unlike another anti-nausea prescription drug available on the market - which is FDA-approved in the United States for treating morning sickness in pregnant women - GSK never conducted a single clinical trial establishing the safety and efficacy of Zofran for treating pregnant women before GSK marketed Zofran for the treatment of pregnant women. GSK, in fact, excluded pregnant women from its clinical trials used to support its application for FDA approval of Zofran. In short, GSK simply chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment during pregnancy. GSK avoided conducting these studies and buried any internal analyses of Zofran's teratogenic potential because they would have hampered its marketing of Zofran and decreased profits by linking the drug to serious birth defects and conditions. GSK's conduct was tantamount to using expectant mothers and their unborn children as human guinea pigs.

4. As a result of GSK's nationwide fraudulent marketing campaign, Zofran was placed into the hands of unsuspecting pregnant women and in the 2000s became the number one most prescribed drug for treating morning sickness in the United States. These women ingested the drug because they innocently believed that Zofran was an appropriate drug for use in their circumstance. When they ingested the drug, these pregnant women had no way of knowing that Zofran had never been studied in pregnant women, much less shown to be a safe and effective treatment for pregnancy-related nausea. Zofran would never have become the most prescribed morning sickness drug in the United States, and Plaintiffs would never have taken the generic bioequivalent of Zofran, if GSK had not misleadingly marketed the drug as a safe and efficacious treatment for morning sickness.

5. By contrast, GSK knew that Zofran was unsafe for ingestion by expectant mothers. In the 1980s, GSK conducted animal studies which revealed evidence of toxicity, intrauterine deaths and malformations in offspring, and further showed that Zofran's active ingredient transferred through the placental barrier of pregnant mammals to fetuses. A later study conducted in humans confirmed that ingested Zofran readily crossed the human placenta barrier and exposed fetuses to substantial concentrations. GSK did not disclose this material information to pregnant women or their physicians.

6. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran. GSK had received at least 32 such reports by 2000, and

has received more than 200 such reports to date, including reports of the same congenital anomalies suffered by A.C. GSK never disclosed these reports to pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological and mechanistic studies that have demonstrated an elevated risk of developing Zofran-induced birth defects such as those suffered in this case. GSK has not disclosed this to pregnant women or their physicians. Instead, GSK sales representatives specifically marketed and promoted Zofran as a morning sickness drug since at least January 1998.

7. In 2012, GSK pled guilty to criminal charges lodged by the United States of America, through the Department of Justice, for its "off-label" promotion of its drugs for uses never approved by the FDA. In exchange for GSK's full performance of its criminal plea agreement with the United States and for certain other promises exchanged between GSK and the United States, the United States agreed not to prosecute GSK criminally for conduct relating to "GSK's sales, marketing and promotion of . . . Zofran between January 1998 and December 2004." (Agreement between United States and GSK, pp. 1-2, June 27, 2012.)

8. Around the same time, GSK also entered civil settlements with United States that included more than \$1 billion in payments to the federal government for its illegal marketing of various drugs, including Zofran specifically.

9. GSK's written agreement with the United States reports GSK's settlement of claims that GSK:

(a) "promoted the sale and use of Zofran for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including hyperemesis and pregnancy-related nausea)"

(b) "made and/or disseminated unsubstantiated and false representations about the safety and efficacy of Zofran concerning the uses described in subsection (a) [hyperemesis and pregnancy-related nausea]"

(b) "offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran"

(Settlement Agreement, p. 5, July 2, 2012.)

10. As the holder of the NDA for Zofran, GSK knew that pharmaceutical companies filing and holding abbreviated new drug applications ("ANDA") would rely on GSK's representations to the FDA, physicians and patients that Zofran was safe and effective. GSK also knew that any generic bioequivalent manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v). GSK further knew that pharmacies in New York and elsewhere routinely substitute less expensive generic drugs such as ondansetron in place of branded drugs such as Zofran. In other words, GSK knew, or should have known that as long as it held the NDA for Zofran, it was responsible for the adequacy of the label and warnings for all forms of ondansetron - whether brand name or generic.

11. GSK's conduct has caused devastating, irreversible, and life-long consequences and suffering to innocent newborns and their families, including Plaintiffs herein.

12. Plaintiff LESLIE COSOLITO's minor child, A.C., was born in 2002 preterm at 36 weeks of gestation, admission problems were discordant twin B, small for gestational age, intrauterine growth restriction and low birth weight. Shortly thereafter she was diagnosed with Autism, Epilepsy, seizures, and low muscle tone after her mother, Plaintiff LESLIE COSOLITO, was prescribed and began taking the generic bioequivalent of Zofran beginning early in her first trimester of pregnancy and took it continuously from then into her second trimester to alleviate and prevent the symptoms of morning sickness.

13. According to A.C.'s treating physician's records, A.C. was born preterm at 36 weeks of gestation, discordant twin B, small for gestational age, intrauterine growth restriction and low birth weight. Shortly thereafter she was diagnosed with Autism, Epilepsy, seizures, and low muscle tone.

14. A.C. was exposed to ondansetron *in utero* during the periods when each of these tissues was forming and susceptible to developmental insult from environmental exposure.

15. A.C. has no family history of any of the conditions from which she suffers. In addition, there has been no indication of a genetic reason for her condition.

16. As a result of her condition, A.C. will require life-long monitoring as she will always be at risk for potentially serious and/or life-threatening conditions.

17. Had Plaintiff LESLIE COSOLITO's prescribing physician known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, she would never have

prescribed Zofran, or generic ondansetron, to LESLIE COSOLITO, and A.C. would never had been injured as described herein.

18. Had Plaintiff known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, she would never have ingested the generic bioequivalent of Zofran and A.C. would never had been injured as described herein.

19. Plaintiffs bring claims for compensatory damages and punitive damages in an effort to ensure that similarly situated mothers-to-be are fully informed about the risks, benefits and alternatives attending drugs marketed for use in pregnant women, and such other relief deemed just and proper arising from injuries and birth defects as a result of exposure to ondansetron.

JURISDICTION AND VENUE

20. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because GSK is a citizen of a state other than the state in which Plaintiffs are citizens.

21. Pursuant to the Transfer Order of the Judicial Panel on Multidistrict Litigation, *In re Zofran (Ondansetron) Products Liab. Litig.*, No. MDL 2657, 2015 WL 6045619, at *1 (Oct. 13, 2015), venue in actions such as this one sharing common questions with the initially transferred actions is proper in this district for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407.

22. Plaintiffs' home district is the United States District Court for the Eastern District of New York. Plaintiffs are domiciled in New York, Plaintiff Cosolito was prescribed ondansetron in New York, she and A.C. were exposed to ondansetron in New York, and they sustained their injuries in New York. In view of the coordination of pretrial proceedings in related Zofran (Ondansetron) actions in this MDL Court, Plaintiffs are filing their claim in the MDL Court for pretrial proceedings, but Plaintiffs assert all of their legal claims under controlling New York substantive law, and Plaintiffs reserve their right to a trial in their home district to the fullest extent permitted by law.

23. Venue in this judicial district is proper under 28 U.S.C. § 1391(a) as Defendant is subject to this court's personal jurisdiction, and Defendant is the only defendant in this action.

24. At all times herein mentioned, GSK conducted, and continues to conduct, a substantial amount of business activity in this judicial district. GSK is registered to conduct business in this district, has maintained at least one office in this district, and has a Resident Agent located in Boston, Massachusetts and engaged in interstate commerce when it advertised, promoted, supplied, and sold pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in

this district. Although GSK's plan to misleadingly market Zofran for pregnancy was devised outside this district, it was executed nationwide, including in this district.

PARTIES

25. Plaintiff, LESLIE COSOLITO, is a citizen of the United States. She is the mother and natural guardian of A.C., who lives with LESLIE COSOLITO. Plaintiff is a citizen and resident of Richmond County, New York.

26. GSK is a limited liability company organized under the laws of the State of Delaware. GSK's sole member is GlaxoSmithKline Holdings, Inc., which is a Delaware corporation, and which has identified its principal place of business in Wilmington, Delaware.

27. GSK is the successor in interest to Glaxo, Inc. and Glaxo Wellcome Inc. Glaxo, Inc. was the sponsor of the original New Drug Application ("NDA") for Zofran. Glaxo, Inc., through its division Cerenex Pharmaceuticals, authored the original package insert and labeling for Zofran, including warnings and precautions attendant to its use. Glaxo Wellcome Inc. sponsored additional NDAs for Zofran, monitored and evaluated post-market adverse event reports arising from Zofran, and authored product labeling for Zofran. The term GSK used herein refers to GSK, its predecessors Glaxo, Inc. and Glaxo Wellcome Inc., and other GSK predecessors and/or affiliates that discovery reveals were involved in the testing, development, manufacture, marketing, sale and/or distribution of Zofran. GSK continued to be the holder of the NDA for Zofran at all times material to this action.

28. At all relevant times, GSK conducted business in the State of New York and has derived substantial revenue from products, including Zofran, sold in New York.

PERTINENT BACKGROUND ON ZOFRAN

29. Zofran is a prescription drug indicated for the prevention of chemotherapy induced nausea and vomiting, radiation therapy-induced nausea and vomiting and post-operative nausea and/or vomiting:

INDICATIONS AND USAGE

1. Prevention of nausea and vomiting associated with highly emetogenic **cancer chemotherapy**, including cisplatin 50 mg/m².
2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic **cancer chemotherapy**.
3. Prevention of nausea and vomiting associated with **radiotherapy** in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
4. Prevention of **postoperative nausea and/or vomiting**.

(GSK, Zofran Prescribing Information, Sept. 2014) (emphasis added.)

30. The medical term for nausea and vomiting is emesis, and drugs that prevent or treat nausea and vomiting are called anti-emetics.

31. Zofran is part of a class of anti-emetics called selective serotonin 5HT₃ receptor antagonists. The active ingredient in Zofran is ondansetron hydrochloride, which is a potent and selective antagonist at the 5-hydroxytryptamine receptor type 3 (5-HT₃).

32. Although 5-hydroxytryptamine (5HT) occurs in most tissues of the human body, Zofran is believed to block the effect of serotonin at the 5HT₃ receptors located along vagal afferents in the gastrointestinal tract and at the receptors located in

the area postrema of the central nervous system (the structure in the brain that controls vomiting). Put differently, Zofran antagonizes, or inhibits, the body's serotonin activity, which triggers nausea and vomiting.

33. Since before GSK began selling Zofran, GSK has known that serotonin also regulates developmental processes that are critical to normal embryonic development. Impeding serotonin signaling during embryonic development can increase the risk of developmental insult to the body's tissues that depend on uninhibited serotonin signaling, including the orofacial region.

34. Zofran was the first 5HT₃ receptor antagonist approved for marketing in the United States. Other drugs in the class of 5HT₃ receptor antagonist include Kytril® (granisetron) (FDA-approved 1994), Anzemet® (dolasetron) (FDA-approved 1997), and Aloxi® (palonosetron) (FDA-approved 2003).

35. Zofran is available as an injection (2 mg/mL), a premixed injection (32 mg/50ml and 4 mg/50 ml), oral tablets (4 mg, 8 mg and 24 mg); orally disintegrating tablets (4 mg and 8 mg) and an oral solution (4 mg/5 mL).

36. More specifically, GSK has obtained FDA approval for the following formations of Zofran:

- a. NDA 20-007 -Zofran Injection (FDA approved January 4, 1991)
- b. NDA 20-103 -Zofran Tablets (FDA approved December 31, 1992)
- c. NDA 20-403 -Zofran Premixed Injection (FDA approved January 31, 1995)
- d. NDA 20-605 -Zofran Oral Solution (FDA approved January 24, 1997)

e. NDA 20-781 – Zofran (a/k/a Zofran-Zydis) Orally Disintegrating Tablets
(FDA approved January 27, 1999)

37. The FDA has never approved Zofran for the treatment of morning sickness or any other condition in pregnant women.

38. For GSK to market Zofran lawfully for the treatment of morning sickness in pregnant women, it must first adequately test the drug (including performing appropriate clinical studies) and formally submit to the FDA evidence demonstrating that the drug is safe and effective for treatment of morning sickness. GSK has not done so.

39. A team of the FDA's physicians, statisticians, chemists, pharmacologists, microbiologists and other scientists would then have an opportunity to: (a) review the company's data and evidence supporting its request for approval to market the drug; and (b) determine whether to approve the company's request to market the drug in the manner requested. Without first obtaining approval to market a drug for the treatment of pregnant women, a pharmaceutical company may not legally market its drug for that purpose.

40. GSK has not performed any clinical studies of Zofran use in pregnant women. GSK, however, had the resources and know-how to perform such studies, and such studies were performed to support another prescription drug that, unlike Zofran, is FDA-approved for the treatment of morning sickness.

41. GSK also has not submitted to the FDA any data demonstrating the safety or efficacy of Zofran for treating morning sickness in pregnant women. Instead, GSK has illegally circumvented the FDA-approval process by marketing Zofran for the treatment of morning sickness in pregnant women without applying for the FDA's approval to market Zofran to treat that condition or any other condition in pregnant women. This practice is known as "off-label" promotion, and in this case it constitutes fraudulent marketing.

42. At all relevant times, GSK was in the business of and did design, research, manufacture, test, package, label, advertise, promote, market, sell and distribute Zofran.

**GSK's Knowledge That Zofran Presents an Unreasonable Risk of Harm to
Babies Who Are Exposed to It During Pregnancy**

Preclinical Studies

43. Since at least the 1980s, when GSK received the results of the preclinical studies that it submitted in support of Zofran's NDA 20-007, GSK has known of the risk that Zofran ingested during pregnancy in mammals crosses the placental barrier to expose the fetus to the drug. For example, at least as early as the mid-1980s, GSK performed placental-transfer studies of Zofran in rats and rabbits, and reported that the rat and rabbit fetuses were exposed prenatally to Zofran during pregnancy.

44. The placental transfer of Zofran during human pregnancy at concentrations high enough to cause congenital malformations has been independently

confirmed and detected in every sample of fetal tissue taken in a published study involving 41 pregnant patients. The average fetal tissue concentration of Zofran's active ingredient was 41% of the corresponding concentration in the mother's plasma.

45. GSK reported four animal studies in support of its application for approval of NDA 20-0007: (1) Study No. R10937 I.V. Segment II teratological study of rats; (2) Study No. R10873 I.V. Segment II teratological study of rabbits; (3) Study No. R10590 Oral Segment II teratological study of rats; (4) Study No. L10649 Oral Segment II teratological study of rabbits. These preclinical teratogenicity studies in rats and rabbits were stated by the sponsor, GSK, to show no harm to the fetus, but the data also revealed clinical signs of toxicity, premature births, intrauterine fetal deaths, and impairment of ossification (incomplete bone growth).

46. Study No. R10937 was a Segment II teratological study of pregnant rats exposed to Zofran injection solution. Four groups of 40 pregnant rats (160 total) were reportedly administered Zofran through intravenous (I.V.) administration at doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. Clinical signs of toxicity that were observed in the pregnant rats included "low posture, ataxia, subdued behavior and rearing, as well as nodding and bulging eyes." No observations were reported as teratogenic effects.

47. Study No. R10873 was a Segment II teratological study of pregnant rabbits exposed to Zofran injection solution. Four groups of 15 pregnant rabbits (60 total) were reportedly given Zofran doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively.

In this study, there was a reported increase in the number of intra-uterine deaths in the 4 mg/kg group versus lower dose groups. The study also reported maternal weight loss in the exposed groups. Developmental retardation in off-spring and fetuses were noted - namely, areas of the parietal (body cavity) were not fully ossified, and the hyoid (neck) failed to ossify completely.

48. Study No. R10590 Oral Segment II teratological study of rats. Four groups of 30 pregnant rats (120 total) were given Zofran orally at doses of 0, 1, 4 and 15 mg/kg/day, respectively. Subdued behavior and labored breathing, which are symptoms of congenital heart defects, and dilated pupils were observed in the 15 mg/kg/day group. Body weight, gestational duration and fetal examinations were reported as normal, but "slight retardation in skeletal ossification" was noted in the offspring.

49. Study No. L10649 Oral Segment II teratological study of rabbits. Four groups of 14-18 pregnant rabbits (56-64 total) were given Zofran orally at doses of 0, 1, 5.5 and 30 mg/kg/day. The study reported lower maternal weight gain in all of the exposed groups, as well as premature delivery and "total litter loss," referring to fetal deaths during pregnancy in the 5.5 mg/kg/day group. Examination of the fetuses showed "slight developmental retardation as evident by incomplete ossification or asymmetry of skeleton."

50. Even if animal studies do not reveal evidence of harm to a prenatally exposed fetus, that result is not necessarily predictive of human response. For example, a drug formerly prescribed to alleviate morning sickness, thalidomide, is an infamous

teratogenic in humans, but animal studies involving the drug failed to demonstrate such an increased risk of birth defects in animals. GSK conducted studies of thalidomide and its toxicity before GSK developed Zofran and before it marketed Zofran for the treatment of morning sickness in pregnant women. Moreover, since at least 1993, GSK has stated in its prescribing information for Zofran that "animal reproduction studies are not always predictive of human response." Therefore, GSK has been aware since at least when it began marketing and selling Zofran that GSK could not responsibly rely on its animal studies as a basis for promoting Zofran use in pregnant women. But that is what GSK did.

Early Reports to GSK of Zofran-Related Birth Defects

51. At least as early as 1992, GSK began receiving reports of birth defects associated with the use of Zofran by pregnant women.

52. By 2000, GSK had received at least 32 reports of birth defects arising from Zofran treatment in pregnant women. These reports included congenital heart disease, dysmorphism, intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomaly, congenital musculoskeletal anomalies, and orofacial anomalies, among others.

53. In many instances, GSK received multiple reports in the same month, the same week and even the same day. For example, on or about September 13, 2000, GSK received three separate reports involving Zofran use and adverse events. For two of those incidents, the impact on the baby was so severe that the baby died.

54. From 1992 to the present, GSK has received more than 200 reports of birth defects in children who were exposed to Zofran during pregnancy.

55. The most commonly reported birth defects arising from Zofran use during pregnancy and reported to GSK were congenital heart defects, though multiple other defects such as orofacial defects, intrauterine death, stillbirth and severe malformations in newborns were frequently reported.

56. The number of events actually reported to GSK was only a small fraction of the actual incidents.

Epidemiology Studies Examining the Risk of Congenital Heart Defects in Babies Who Were Exposed to Zofran During Pregnancy

57. Epidemiology is a branch of medicine focused on studying the causes, distribution, and control of diseases in human populations.

58. At least three recent epidemiological studies have examined the association between prenatal exposure to Zofran and the risk of congenital heart defects in babies. These studies include: (1) Pasternak, et al., *Ondansetron in Pregnancy and Risk of Adverse Fetal Outcomes*, New England Journal of Medicine (Feb. 28, 2013) (the "Pasternak Study"); (2) Andersen, et al., *Ondansetron Use in Early Pregnancy and the Risk of Congenital Malformations-A Register Based Nationwide Control Study*, presented at International Society of Pharmaco-epidemiology, Montreal, Canada (2013) (the "Andersen Study"); and (3) Danielsson, et al., *Ondansetron During Pregnancy and Congenital Malformations in the Infant* (Oct. 31, 2014) (the "Danielsson Study").

59. Each of these studies includes methodological characteristics tending to bias its results toward under-reporting the true risk of having a child with a birth defect. Notwithstanding these characteristics biasing the results toward the null hypothesis, all three studies show elevated risk ratios for cardiac malformations, including risk ratios greater than 2.0. In other words, the studies report that a mother exposed to Zofran had more than a doubled risk of having a baby with a congenital heart defect as compared to a mother who did not ingest Zofran during pregnancy.

60. The Pasternak Study included data from the Danish National Birth Registry and examined the use of Zofran during pregnancy and risk of adverse fetal outcomes. Adverse fetal outcomes were defined as: spontaneous abortion, stillbirth, any major birth defect, pre-term delivery, low birth weight, and small size for gestational age. There were 608,385 pregnancies between January 2004 and March 31, 2011 examined. The unexposed group was defined as women who did not fill a prescription for ondansetron during the exposure time window. The exposure time window was defined as the first 12 week gestational period. Notably, the median fetal age at first exposure to Zofran was ten weeks, meaning that half of the cases were first exposed to Zofran after organogenesis (organ formation). This characteristic of the study led to an under-reporting of the actual risk of prenatal Zofran exposure. The study's supplemental materials indicated that women taking Zofran during the first trimester, compared to women who did not take Zofran, were 22% more likely to have offspring with a septal defect, 41% more likely to have offspring with a ventricular

septal defect and greater than four-times more likely to have offspring with atrioventricular septal defect.

61. The Andersen Study was also based on data collected from the Danish Medical Birth Registry and the National Hospital Register, the same data examined in the Pasternak Study. The Andersen study examined the relationship between Zofran use during the first trimester and subgroups of congenital malformations. Data from all women giving birth in Denmark between 1997 and 2010 were included in the study. A total of 903,207 births were identified in the study period with 1,368 women filling prescriptions for Zofran during the first trimester. The Andersen Study therefore used a larger data set (13 years) compared to the Pasternak Study (seven years). Exposure to the drug was also defined as filling a prescription during the first trimester, and prescription data were obtained from the National Prescription Registry. The Andersen study reported that mothers who ingested Zofran during their first trimester of pregnancy were more likely than mothers who did not to have a child with a congenital heart defect, and had a two- to four-fold greater risk of having a baby with a septal cardiac defect.

62. The Danielsson Study investigated risks associated with Zofran use during pregnancy and risk of cardiac congenital malformations from data available through the Swedish Medical Birth Registry. The Swedish Medical Birth Registry was combined with the Swedish Register of Prescribed Drugs to identify 1,349 infants born to women who had taken Zofran in early pregnancy from 1998-2012. The total number of births in the study was 1,501,434 infants, and 43,658 had malformations classified as

major (2.9%). Among the major malformations, 14,872 had cardiovascular defects (34%) and 10,491 had a cardiac septum defect (24%). The Danielsson study reported a statistically significantly elevated risk for cardiovascular defects for mothers taking Zofran versus those who did not. The results reported that the mothers who took Zofran during early pregnancy had a 62% increased risk of having a baby with a cardiovascular defect. Further, mothers who took Zofran during pregnancy had a greater than two-fold increased risk of having a baby with a septal cardiac defect, compared to mothers who did not take Zofran during pregnancy.

63. In summary, since at least 1992, GSK has had mounting evidence showing that Zofran presents an unreasonable risk of harm to babies who are exposed to the drug during pregnancy. GSK has been aware that Zofran readily crosses human placental barriers during pregnancy. GSK has also been aware that the animal studies of Zofran cannot reliably support an assertion that Zofran can be used safely or effectively in pregnant women. Since 1992, GSK has received hundreds of reports of major birth defects associated with prenatal Zofran exposure. GSK also has had actual and/or constructive knowledge of the epidemiological studies reporting that prenatal Zofran exposure can more than double the risk of developing congenital heart defects. As alleged below, GSK not only concealed this knowledge from healthcare providers and consumers in the United States, and failed to warn of the risk of birth defects, but GSK also illegally and fraudulently promoted Zofran to physicians and patients specifically for the treatment of morning sickness in pregnancy women.

**GSK's Failure to Warn of the Risk of Birth Defects
Associated with Prenatal Exposure to Zofran**

64. Under federal law governing GSK's drug labeling for Zofran, GSK was required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." 21 C.F.R. § 201.57(e).

65. GSK was also required to list adverse reactions that occurred with other drugs in the same class as Zofran. *Id.* § 201.57(g).

66. In the context of prescription drug labeling, "an adverse reaction is an undesirable effect, reasonably associated with use of a drug, which may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." *Id.*

67. Federal law also required GSK to revise Zofran's labeling "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." *Id.* § 201.57(e) (emphasis added).

68. GSK has received hundreds of reports of birth defects associated with the non- FDA-approved use of Zofran in pregnant women. GSK has failed, however, to disclose these severe adverse events to healthcare providers or expectant mothers, including LESLIE COSOLITO and her prescribing healthcare provider.

69. Under 21 C.F.R. § 314.70(c)(2)(i), pharmaceutical companies were (and are) free to add or strengthen - without prior approval from the FDA - a contraindication, warning, precaution, or adverse reaction.

70. GSK thus had the ability and obligation to add warnings, precautions and adverse reactions to the product labeling for Zofran without prior approval from the FDA. GSK failed to do so. Had GSK done so, the manufacturers of generic bioequivalent versions of Zofran would have been required to make the same additions. *Id.* at 660-661.

71. Under 21 C.F.R. § 201.128, "if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put."

72. At least as of 1998, GSK knew well from its off-label promotion and payments to doctors, and its conspicuous increase in revenue from Zofran, and its market analyses of prescription data, that physicians were prescribing Zofran off-label to treat morning sickness in pregnant women and that such usage was associated with a clinically significant risk or hazard - birth defects.

73. GSK had the ability and obligation to state prominently in the Indications and Usage section of its drug label that there is a lack of evidence that Zofran is safe for the treatment of morning sickness in pregnant women. GSK failed to do so, despite GSK's

knowledge that (a) the safety of Zofran for use in human pregnancy has not been established, and (b) there have been hundreds of reports of birth defects associated with Zofran use during pregnancy, and (c) epidemiology studies report an increased risk of birth defects in babies exposed to Zofran during pregnancy.

74. From 1993 to the present, despite mounting evidence of the birth defect risk, GSK's prescribing information for Zofran has included the same statement concerning use of Zofran during pregnancy:

"Pregnancy:Teratogenic Effects: Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at I.V. doses up to 4 mg/kg per day and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed."

75. By contrast, the Product Monograph for Zofran in Canada states "the safety of ondansetron for use in human pregnancy has not been established," and that "the use of ondansetron in pregnancy is not recommended."

76. In the United States and in New York specifically, GSK has at all relevant times failed to include any warning disclosing any risks of birth defects arising from Zofran use during pregnancy in Zofran's prescribing information or other product labeling.

77. GSK's inclusion of the phrase "Pregnancy Category B" in Zofran's prescribing information refers the FDA's pregnancy categorization scheme applicable to prescription drugs in the United States. The FDA has established five categories to indicate the potential of a drug to cause birth defects if used during pregnancy. The

current system of pregnancy labeling consists of five letter-categories (A, B, C, D, and X, in order of increasing risk).

78. GSK had the ability, and indeed was required, to update Zofran's label to reflect at best a Pregnancy Category D designation or alternatively a Category X designation for Zofran:

Pregnancy Category D. If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: "Pregnancy Category D. See "Warnings and Precautions" section. Under the "Warnings and Precautions" section, the labeling must state: "[drug] can cause fetal harm when administered to a pregnant woman . . . If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."

21 C.F.R. § 201.57(f)(6)(i)(d) (emphasis added).

Pregnancy Category X. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: "Pregnancy Category X. See 'Contraindications' section." Under "Contraindications," the labeling must state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman. . . . (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."

Id. § 201.57(f)(6)(i)(e) (emphasis added).

79. Beginning at least in 1992, GSK had positive evidence of human fetal risk posed by Zofran based more than 200 reports to GSK of birth defects, as well as epidemiology studies, and placental-transfer studies reporting on Zofran's teratogenic risk. GSK has never updated Zofran's labeling to disclose that Zofran can cause fetal harm when administered to a pregnant woman, and GSK has failed to warn of the potential hazards to a fetus arising from Zofran use during pregnancy.

80. The FDA recently promulgated a final rule declaring that, as of June 2015, it will require pharmaceutical manufacturers to remove the current A, B, C, D, or X pregnancy categorization designation from all drug product labeling and instead summarize the risks of using a drug during pregnancy, discuss the data supporting that summary, and describe relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. 79 Fed. Reg. 72064 (Dec. 4, 2014). In promulgating this rule, the FDA "determined that retaining the pregnancy categories is inconsistent with the need to accurately and consistently communicate differences in degrees of fetal risk."

81. In summary, beginning years before Plaintiffs were exposed to Zofran, GSK marketed and sold Zofran without adequate warning to healthcare providers and consumers that Zofran was causally associated with an increased risk of birth defects, and that GSK had not adequately tested Zofran to support marketing and promotion it for use in pregnant women. This rendered the warnings accompanying Zofran inadequate and defective.

82. Plaintiffs hereby demand that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiffs and similarly situated mothers and mothers-to-be, as GSK's wrongful conduct alleged herein is continuing. Plaintiffs further demand that GSK fully and fairly comply to remove the Pregnancy Category B designation from its drug product labeling for Zofran and fully and accurately summarize the risks of using Zofran during pregnancy, fully and accurately describe the data supporting that summary, and fully and accurately describe the relevant information to help health care providers make informed prescribing decisions and counsel women about the risks associated with use of Zofran during pregnancy.

**GSK's Fraudulent, Off-Label Promotion of Zofran
for the Treatment of Morning Sickness in Pregnant Women**

83. At all relevant times, GSK has known that the safety of Zofran for use in human pregnancy has not been established.

84. But with more than six million annual pregnancies in the United States since 1991 and an estimated 70-85% incidence of pregnancy-related nausea, the absence of a prescription medication that was approved by the FDA for pregnancy-related nausea presented an extremely lucrative business opportunity for GSK to expand its sales of Zofran. GSK seized that opportunity, but the effect of its conduct was tantamount to experimenting with the lives of unsuspecting mothers-to-be and their babies in the United States and in New York.

85. At least as early as January 1998, despite available evidence showing that Zofran presented an unreasonable risk of harm to babies exposed to Zofran prenatally,

GSK launched a marketing scheme to promote Zofran to obstetrics and gynecology (Ob/Gyn) healthcare practitioners including those in New York, among others, as a safe treatment alternative for morning sickness in pregnant women.

86. In support of its off-label marketing efforts, at least as early as January 1998, GSK offered and paid substantial remuneration to healthcare providers and "thought leaders" to induce them to promote and prescribe Zofran to treat morning sickness.

87. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) notified GSK that the FDA had become aware of GSK's promotional materials for Zofran that violated the Federal Food Drug and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance." (FDA Ltr. to Michele Hardy, Director, Advertising and Labeling Policy, GSK, Mar. 9 1999.)

88. GSK's promotional labeling under consideration included promotional statements relating the effectiveness of Zofran, such as "Zofran Can," "24-hour control," and other promotional messages. But the promotional labeling failed to present any information regarding the risks associated with use of Zofran.

89. In its March 9, 1999 letter, the FDA directed GSK to "immediately cease distribution of this and other similar promotional materials for Zofran that contain the same or similar claims without balancing risk information."

90. GSK blatantly disregarded this mandate by the FDA. For example, in 2002, GSK's marketing materials to Ob/Gyn practitioners emphasized Zofran's "Pregnancy Category B" designation on the very first page of the marketing material, creating a false impression that the safety of use in pregnancy has been established. GSK's materials failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran treatment during pregnancy.

91. When Zofran was first approved by the FDA to treat cancer patients, GSK's Oncology Division sales force had primary responsibility for marketing and promoting the drug. Beginning in at least January 1998, GSK set out to expand its Zofran sales to obstetricians and gynecologists by promoting Zofran as an established safe and effective treatment for morning sickness. GSK's initial strategy in this regard required its sales force to create new relationships with obstetricians and gynecologists by adding them as "new accounts." While this strategy had some success, it was inefficient compared to a revised promotional strategy that would enable GSK to leverage its other Division's already established relationships with obstetricians and gynecologists. Thus, GSK's Oncology Division began partnering with GSK's Consumer Healthcare Division to promote Zofran.

92. Specifically, in or about 2001, GSK's Oncology Division finalized a co-marketing agreement with GSK's Consumer Healthcare division under which sales representatives from GSK's Consumer Healthcare division would market Zofran to obstetricians and gynecologists. At the time GSK's Consumer Healthcare sales force

already had established relationships with, and routinely called on, obstetricians and gynecologists to promote and provide samples of another GSK product, Tums, specifically for the treatment and prevention of heartburn during pregnancy. GSK's established network for promoting Tums for use in pregnancy afforded it an efficient additional conduit for promoting Zofran for use in pregnancy.

93. GSK's primary purpose in undertaking this co-marketing arrangement was to promote Zofran to obstetricians and gynecologists during GSK's Consumer Healthcare sales force's visits to obstetricians and gynecologists offices. Although some obstetricians and gynecologists performed surgeries and could order Zofran for post-operative nausea, the central focus of GSK's co-marketing effort was to promote Zofran for the much more common condition of morningsickness in pregnancy, and thus increase sales and profits.

94. GSK's Zofran sales representatives received incentive-based compensation that included an annual salary and a quarterly bonus. The bonus amount was determined by each sales representative's performance in the relevant market and whether s/he attained or exceeded quarterly sales quotas. The more Zofran sold by a GSK sales representative or prescribed by a provider in that representative's sales territory, the greater his or her compensation and other incentives would be.

95. As a result of GSK's fraudulent marketing campaign, the precise details of which are uniquely within the control of GSK, Zofran achieved blockbuster status by 2002 and became the number one most prescribed drug for treating morning sickness in

the United States. In 2002, sales of Zofran in the United States totaled \$1.1 billion, while global Zofran sales were approximately \$1.4 billion in 2002.

96. GSK's promotion of Zofran for use in pregnancy eventually led to a federal governmental investigation. On July 2, 2012 the Department of Justice announced that GSK "agreed to plead guilty and pay \$3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs," which included Zofran among numerous others. See DOJ Press Release, *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012).

97. Part of GSK's civil liability to the government included payments arising from the facts that: (a) GSK promoted Zofran and disseminated false representations about the safety and efficacy of Zofran concerning pregnancy-related nausea and hyperemesis gravidarum, a severe form of morning sickness; and (b) GSK paid and offered to pay illegal remuneration to health care professionals to induce them to promote and prescribe Zofran.

98. GSK's 2012 civil settlement with the United States covered improper promotional conduct that was part of an overarching plan to maximize highly profitable Zofran sales without due regard to laws designed to protect patient health and safety. Another component of that plan led to a separate \$150 million settlement between GSK and the United States in 2005. In or around 1993, a GSK marketing document sent to all of its sales and marketing personnel nationwide advised that they should

emphasize to medical providers not only the benefits of Zofran but also the financial benefits to the providers by prescribing Zofran. Specifically, "[b]y using a 32 mg bag [of Zofran], the physician provides the most effective dose to the patient and increases his or her profit by \$___ in reimbursement." GSK's marketing focus on profits to the prescribers misleadingly aimed to shift prescribers' focus from the best interests of patients to personal profit. In this regard, GSK marketed Zofran beginning in the 1990s as "convenient" and offering "better reimbursement" to prescribers. GSK detailed this plan in a marketing document for its Zofran premixed IV bag entitled "Profit Maximization - It's in the Bag." Upon information and belief, GSK's conduct in this paragraph continued until the DOJ began investigating it in the early 2000s.

Plaintiffs' Exposures to Ondansetron

99. Plaintiff LESLIE COSOLITO is the mother and natural guardian of A.C.

100. To alleviate and prevent the symptoms of morning sickness, Plaintiff LESLIE COSOLITO was prescribed Zofran's generic bioequivalent, beginning in her first trimester of pregnancy with A.C. She took the medication as directed and continued taking the generic bioequivalent of Zofran as needed into her second trimester.

101. A.C. was born in 2002.

102. According to A.C.'s treating physician's records, A.C. was born preterm at 36 weeks of gestation, admission problems were discordant twin B, small for gestational age, intrauterine growth restriction and low birth weight.

103. A.C. was exposed to ondansetron *in utero* during the periods when each of these tissues was forming and susceptible to developmental insult from environmental exposure.

104. A.C. has no family history of any of the conditions from which she suffers. In addition, there has been no indication of a genetic reason for her conditions.

105. Plaintiff LESLIE COSOLITO was unaware of the dangerousness of ondansetron or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took the generic bioequivalent of Zofran during pregnancy.

106. Had Plaintiff's prescribing physician known of the increased risk of birth defects associated with Zofran, and had she not been misled by GSK's promoting the drug's purported safety benefits for use in pregnancy (on which she reasonably relied), she would not have prescribed Zofran to LESLIE COSOLITO and A.C. would never have been injured as described herein.

107. Had Plaintiff LESLIE COSOLITO known of the increased risk of birth defects associated with Zofran, and had she not been misled by GSK's promoting the drug's purported safety benefits for use in pregnancy (on which she reasonably relied), Plaintiff would not have taken the generic bioequivalent of Zofran during pregnancy and A.C. would not have been born with congenital malformations.

108. As a direct and proximate result of GSK's conduct, Plaintiffs LESLIE COSOLITO and her daughter A.C. have suffered and incurred harm including severe and permanent pain and suffering, mental anguish, medical expenses and other

economic and noneconomic damages, and will require more constant and continuous medical monitoring and treatment than had they not been exposed to ondansetron.

109. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that GSK caused the appreciable harm sustained by her daughter, A.C. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the injuries at an earlier time. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, the tortious nature of the conduct causing the injuries, until a short time before filing of this action. Additionally, Plaintiffs were prevented from discovering this information sooner because GSK has misrepresented to the public and to the medical profession that Zofran is safe for use in pregnancy, and GSK has fraudulently concealed facts and information that could have led Plaintiffs to discover a potential cause of action. In all events, the statute of limitations is tolled for claims arising from injuries to minors.

110. All causes of action herein are pleaded under the controlling substantive law of New York, the state of Plaintiffs' home forum.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

111. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

112. GSK had a duty to exercise reasonable care, and comply with existing standards of care, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, and/or distribution of Zofran into the stream of commerce, including a duty to ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

113. GSK failed to exercise ordinary care and failed to comply with existing standards of care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

114. GSK, its agents, servants, and/or employees, failed to exercise ordinary care and failed to comply with existing standards of care in the following acts and/or omissions:

- a. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety risks of Zofran for treating pregnant women while promoting the use of Zofran and providing kickbacks to health care professionals to convince health care professionals to prescribe Zofran for pregnancy-related nausea;
- b. Marketing Zofran for the treatment of morning sickness in pregnant women without testing it to determine whether or not Zofran was safe for this use;

- c. Designing, manufacturing, producing, promoting, formulating, creating, and/or designing Zofran without adequately and thoroughly testing it;
- d. Selling Zofran without conducting sufficient tests to identify the dangers posed by Zofran to pregnant women;
- e. Failing to adequately and correctly warn the Plaintiffs, the public, the medical and healthcare profession, ondansetron ANDA holders, and the FDA of the dangers of Zofran for pregnant women;
- f. Failing to evaluate available data and safety information concerning Zofran use in pregnant women;
- g. Advertising and recommending the use of Zofran without sufficient knowledge as to its dangerous propensities to cause birth defects;
- h. Representing that Zofran was safe for treating pregnant women, when, in fact, it was and is unsafe;
- i. Representing that Zofran was safe and efficacious for treating morning sickness and hyperemesis gravidarum when GSK was aware that neither the safety nor efficacy for such treatment has been established;
- j. Representing that GSK's animal studies in rats and rabbits showed no harm to fetuses, when the data revealed impairment of ossification (incomplete bone growth) and other signs of toxicity;
- k. Failing to provide adequate instructions regarding birth defects including cleft palate and cardiac malformations;
- l. Failing to accompany Zofran with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Zofran;
- m. Failing to include a black box warning concerning the birth defects associated with Zofran;
- n. Failing to issue sufficiently strengthened warnings following the existence of reasonable evidence associating Zofran use with the increased risk of birth defects;

- o. Failing to advise Plaintiffs, her healthcare providers, FDA, ondansetron ANDA holders and the medical community that neither the safety nor the efficacy of Zofran for treating pregnancy-related nausea has been established and that the risks of the using the drug for that condition outweigh any putative benefit;
- p. Failing to advise Plaintiffs, her healthcare providers, FDA, ondansetron ANDA holders and the medical community of clinically significant adverse reactions (birth defects) associated with Zofran use during pregnancy; and
- q. Failing to correct its misrepresentations that the safety and efficacy of Zofran for treating morning sickness had been established.

115. Despite the fact that GSK knew or should have known that Zofran significantly increased the risk of birth defects, GSK continued and continue to negligently and misleadingly market, manufacture, distribute and/or sell Zofran to consumers, including Plaintiffs.

116. GSK knew or should have known that consumers such as Plaintiffs would foreseeably use the generic bioequivalent of Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

117. GSK knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care, as set forth above.

118. GSK's negligence was the proximate cause of Plaintiffs' injuries, harm and economic loss, which Plaintiffs suffered and/or will continue to suffer.

119. Had Plaintiff LESLIE COSOLITO not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a truthful and non-misleading manner, Plaintiff's physician would not have prescribed Zofran and LESLIE COSOLITO would not have taken the generic bioequivalent of Zofran.

120. As a result of the foregoing acts and omissions, A.C. was caused to suffer serious birth defects and conditions that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

121. As a result of the foregoing acts and omissions, Plaintiff A.C. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff LESLIE COSOLITO is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

122. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct and demand judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
(NEGLIGENCE PER SE)

123. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

124. GSK had a duty to exercise reasonable care, and comply with existing laws, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, and/or distribution of Zofran into the stream of commerce, including a duty to ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

125. GSK failed to exercise ordinary care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

126. GSK, its agents, servants, and/or employees, failed to exercise ordinary care and violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.128, in particular.

127. The laws violated by GSK were designed to protect Plaintiffs and similarly situated persons and protect against the risks and hazards that have actualized in this case. Therefore, GSK's conduct constitutes negligence per se.

128. Despite the fact that GSK knew or should have known that Zofran significantly increased the risk of birth defects, GSK continued and continue to negligently and misleadingly market, manufacture, distribute and/or sell Zofran to consumers, including Plaintiffs.

129. GSK knew or should have known that consumers such as Plaintiffs would foreseeably use the generic bioequivalent of Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

130. GSK knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care, as set forth above.

131. GSK's negligence was the proximate cause of Plaintiffs' injuries, harm and economic loss, which Plaintiffs suffered and/or will continue to suffer.

132. Had Plaintiff LESLIE COSOLITO not taken Zofran, her baby would not have suffered those injuries and damages as described herein.

133. As a result of the foregoing acts and omissions, A.C. was caused to suffer serious birth defects and conditions that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

134. As a result of the foregoing acts and omissions, Plaintiff A.C. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff LESLIE COSOLITO is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

135. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

THIRD CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

136. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

137. GSK committed actual and constructive fraud. GSK committed actual fraud by misrepresenting material facts on which Plaintiff LESLIE COSOLITO and her healthcare providers acted. GSK committed constructive fraud by acting contrary to legal or equitable duties, trust, or confidence upon which Plaintiffs relied, and by failing to act, though it should have. GSK's conduct constitutes constructive fraud because GSK breached legal and equitable duties and violated its fiduciary relationships to patients and healthcare providers.

138. GSK had a duty to exercise reasonable care to those to whom it provided product information about Zofran and to all those relying on the information provided, including Plaintiff LESLIE COSOLITO and her healthcare providers.

139. GSK had a duty to exercise reasonable care to those to whom it provided product information about Zofran and to all those relying on the information provided, including Plaintiff and her healthcare providers.

140. In violations of existing standards and duties of care, GSK made misrepresentations by means including, but not limited to, advertisements, labeling, marketing, marketing persons, notices, product information and written and oral information provided to patients and medical providers.

141. In violations of existing standards and duties of care, GSK intentionally, knowingly, falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff LESLIE COSOLITO and her providers, that:

- a. Zofran was safe and effective for treating pregnancy-related nausea;
- b. Zofran had been adequately tested and studied in pregnant women;
- c. Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and
- d. Zofran's "Pregnancy Category B" designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

142. The representations made by GSK were material, false and misleading.

143. When GSK made these representations, it knew they were false.

144. GSK made these representations with the intent of defrauding and deceiving the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, including Plaintiffs and her providers, to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy-related nausea.

145. At the time the aforesaid representations were made by GSK and, at the time Plaintiffs used the generic bioequivalent of Zofran, she was unaware of the falsity of said representations and reasonably believed them to be true.

146. In reasonable reliance upon said representations, Plaintiff LESLIE COSOLITO's prescriber was induced to prescribe Zofran and/or its generic bioequivalent to her and recommend the drug as safe for treating pregnancy-related nausea, and Plaintiff LESLIE COSOLITO was induced to and did use the generic bioequivalent of Zofran to treat pregnancy-related nausea. Had GSK not made the foregoing express and implied false statements about the product, Plaintiff LESLIE COSOLITO's physician would not have recommended or prescribed Zofran and Plaintiff LESLIE COSOLITO would not have used the product.

147. GSK knew that Zofran had not been sufficiently tested for pregnancy-related nausea and that it lacked adequate warnings.

148. GSK knew or should have known that Zofran increases expectant mothers' risk of developing birth defects.

149. GSK knew or should have known that consumers such as Plaintiffs would foreseeably use the generic bioequivalent of Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

150. As a result of the foregoing acts and omissions, A.C. was caused to suffer birth defects that are permanent and lasting in nature, as well as physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

151. As a result of the foregoing acts and omissions, Plaintiff A.C. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff LESLIE COSOLITO is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

152. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct and demand judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

153. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

154. GSK had a duty to exercise reasonable care to those to whom it provided product information about Zofran and to all those relying on the information provided, including Plaintiff and her healthcare providers. GSK had exclusive access to material information about the teratogenic risks of Zofran, and GSK knew that neither Plaintiff LESLIE COSOLITO nor her medical providers could reasonably discover that information.

155. In violations of the existing standards and duties of care, GSK fraudulently concealed and intentionally omitted material facts in representations by means including, but not limited to advertisements, labeling, marketing, marketing persons, notices, product information and written and oral information provided to patients, medical providers, generic bioequivalent ANDA holders, and the FDA.

156. In violations of the existing standards and duties of care, in representations to Plaintiff LESLIE COSOLITO's healthcare providers, expectant mothers including Plaintiff LESLIE COSOLITO, generic bioequivalent ANDA holders and the FDA, GSK fraudulently concealed and intentionally omitted the following material facts:

- a. GSK was illegally paying and offering to pay doctors remuneration to promote and prescribe Zofran;
- b. Zofran had not (and has not) been tested or studied in pregnant women at all;
- c. *in utero* Zofran exposure increases the risk of serious birth defects and conditions;
- d. independent researchers have reported in peer-reviewed literature that *in utero* Zofran exposure increases the risk of serious birth defects and conditions;

- e. the risks of serious birth defects and conditions associated with the consumption of Zofran by pregnant women were not adequately tested prior to GSK's marketing of Zofran;
- f. the safety and efficacy of Zofran for treating pregnancy-related nausea has not been established;
- g. Zofran is not safe and effective for treating pregnancy-related nausea; and
- h. GSK's internal data and information signaled an association between Zofran uses during pregnancy with serious birth defects and conditions.

157. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran for pregnancy-related nausea was made purposefully, willfully, wantonly, and/or recklessly, to mislead physicians, hospitals and healthcare providers, and expectant mothers including Plaintiff LESLIE COSOLITO into reliance, continued use of Zofran or generic bioequivalent, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

158. GSK knew that physicians, hospitals, healthcare providers and expectant mothers such as Plaintiff LESLIE COSOLITO had no way to determine the truth behind GSK's concealment and material omissions of facts surrounding Zofran, as set forth herein.

159. Plaintiff LESLIE COSOLITO and her providers reasonably relied on GSK's promotional statements concerning Zofran's asserted safety and efficacy in pregnant women, from which GSK negligently, fraudulently and/or purposefully omitted material facts. Had GSK disclosed the material omissions about the product, Plaintiff LESLIE COSOLITO would not have used the generic bioequivalent and her providers would not

have prescribed Zofran and at a minimum would have communicated to Plaintiff LESLIE COSOLITO the pregnancy risks and how to avoid them.

160. As a result of the foregoing acts and omissions, A.C. was caused to suffer serious serious birth defects and conditions and conditions and conditions, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

161. As a result of the foregoing acts and omissions, Plaintiff A.C. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff LESLIE COSOLITO is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

162. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct and demand judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

163. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

164. Defendant GSK had a duty to exercise reasonable care to those to whom it provided product information about Zofran and to all those relying on the information provided, including Plaintiffs and her healthcare providers.

165. Defendant GSK owed a duty in all of its several undertakings, including the dissemination of information concerning Zofran and ondansetron, to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of harm to others.

166. In violation of the existing standards and duties of care, GSK materially misrepresented and omitted complete and accurate information in Zofran's labeling, advertising, marketing, sales and marketing persons, notices, oral promotional efforts, and product information concerning the nature, character, quality, safety, and proper use of their product. Specifically, these misrepresentations GSK falsely and negligently represented to the medical community and expectant mothers, including Plaintiff LESLIE COSOLITO and her healthcare providers, include, but are not limited to the following:

- a. Zofran was safe and effective for treating pregnancy-related nausea;
- b. Zofran had been adequately tested and studied in pregnant women;
- c. Zofran use during pregnancy did not increase the risk of bearing children with serious birth defects and conditions; and
- d. Zofran's "Pregnancy Category B" designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

167. The representations made by GSK were, in fact, false and misleading.

168. Plaintiff LESLIE COSOLITO and her providers reasonably relied upon GSK's expertise, skill, judgment, and knowledge and upon their express and/or implied warranties that their product was safe, efficacious, adequately tested, of merchantable quality and fit for use during pregnancy. In justifiable reliance upon these misrepresentations, Plaintiff LESLIE COSOLITO and her providers were induced to prescribe and use Zofran or its generic bioequivalent.

169. Had GSK not made express and implied false statements, or revealed all material information about Zofran, Plaintiff LESLIE COSOLITO's providers would not have prescribed it and Plaintiff LESLIE COSOLITO would not have used the generic bioequivalent.

170. As a result of the foregoing acts and omissions, A.C. has suffered serious birth defects and conditions, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

171. As a proximate and foreseeable result of this dissemination of negligently false information, the Plaintiffs suffered grievous bodily injury and consequent economic and other loss as described above, when her physicians, in reasonable reliance upon the negligently inaccurate misleading and otherwise false information disseminated by GSK, and reasonably but unjustifiably believing the information to be true, prescribed LESLIE COSOLITO the use of Zofran and/or ondansetron products for a

prolonged and unwanted period of time and she ingested, per these prescriptions, ondansetron products, leading to A.C. to suffer serious birth defects and conditions.

172. As a result of the foregoing acts and omissions, Plaintiff A.C. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff LESLIE COSOLITO is informed and believes and further alleges that A.C. will in the future be required to obtain further medical and/or hospital care, attention, and services.

173. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct and demand judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

174. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

175. At all times herein mentioned, the Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendant who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Zofran as hereinabove described that was used by the Plaintiff.

176. That Zofran was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

177. At those times, Zofran was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

178. Zofran which was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Zofran.

179. Zofran which was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective in design and/or formulation, in that, when it left the hands of the Defendant manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

180. At all times herein mentioned, Zofran was in a defective condition and unsafe, and Defendant knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendant.

181. Defendant knew or should have known that at all times herein mentioned, Zofran was in a defective condition, and was and is inherently dangerous and unsafe.

182. At the time of the Plaintiff's use of Zofran, Zofran was being used to treat pregnancy-related nausea.

183. Defendant with this knowledge voluntarily designed its Zofran in a dangerous condition for use by the public, and in particular the Plaintiff.

184. Defendant had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

185. Defendant created a product unreasonably dangerous for its normal, intended use.

186. Zofran which was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was manufactured defectively in that Zofran left the hands of Defendant in a defective condition and was unreasonably dangerous to its intended users.

187. Zofran which was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant reached their intended users in the same defective and unreasonably dangerous condition in which the Defendant's Zofran was manufactured.

188. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendant are therefore strictly liable for the injuries sustained by the Plaintiff.

189. The Plaintiff could not by the exercise of reasonable care, have discovered Zofran's defects herein mentioned and perceived its danger.

190. Zofran which was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate warnings or instructions as the Defendant knew or should have known that the product created risk of serious birth defects and conditions associated with it, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendant failed to adequately warn of said risk.

191. Zofran which was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate warnings and/or inadequate testing.

192. Zofran which was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risk of serious birth defects and conditions associated with it, as well as other severe and permanent health consequences from Zofran, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Zofran.

193. By reason of the foregoing, the Defendant has become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Zofran.

194. Defendant's defective design, manufacturing defect, and inadequate warnings of Zofran were acts that amount to willful, wanton, and/or reckless conduct by Defendant.

195. That said defects in Defendant's drug Zofran were a substantial factor in causing Plaintiff's A.C.'s injuries.

196. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, leading to A.C. to suffer serious birth defects and conditions as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any other health consequences.

197. As a result of the foregoing acts and omissions the Plaintiff A.C. requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

198. By reason of the foregoing, Plaintiffs demand judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

199. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

200. Defendant expressly warranted that Zofran was safe and well accepted by users.

201. The anti-nausea medication, Zofran does not conform to these express representations because Zofran is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendant. As a direct and proximate result of the breach of said warranties, Plaintiff A.C. suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

202. Plaintiff did rely on the express warranties of the Defendant herein.

203. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendant for use of Zofran in recommending, prescribing, and/or dispensing Zofran.

204. The Defendant herein breached the aforesaid express warranties, as their drug Zofran was defective.

205. Defendant expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that Zofran was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of anti-nausea medication, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

206. Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Zofran was not safe and fit for

the use intended, and, in fact, produced serious birth defects to the users that were not accurately identified and represented by Defendant.

207. As a result of the foregoing acts and/or omissions the Plaintiff A.C., was and still is caused to suffer serious birth defects and conditions, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

208. By reason of the foregoing, Plaintiff A.C. has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment.

209. As a result of the foregoing acts and omissions the Plaintiff A.C. requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

210. By reason of the foregoing, Plaintiffs demand judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTIES)

211. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

212. At all times herein mentioned, the Defendant manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Zofran and/or have recently acquired the Defendant who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Zofran, for use in contraception.

213. At the time Defendant marketed, sold, and distributed Zofran for use by Plaintiff, Defendant knew of the use for which Zofran was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

214. The Defendant impliedly represented and warranted to the users of Zofran and their physicians, healthcare providers, and/or the FDA that Zofran was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

215. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Zofran was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

216. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

217. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendant as to whether Zofran was of merchantable quality and safe and fit for its intended use.

218. The anti-nausea medication, Zofran was injected into the stream of commerce by the Defendant in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

219. The Defendant herein breached the aforesaid implied warranties, as their drug Zofran was not fit for its intended purposes and uses.

220. As a result of the foregoing acts and omissions, Plaintiff A.C., was and still is caused to suffer serious birth defects and conditions, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

221. As a result of the foregoing acts and omissions the Plaintiff A.C. requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges

that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

222. By reason of the foregoing, Plaintiffs demand judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION
(UNFAIR AND DECEPTIVE TRADE PRACTICES/
NEW YORK CONSUMER PROTECTION ACT VIOLATION)

223. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

224. Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

225. New York provides protection to consumer of products including drugs, also known as goods, by the General Business Law §§359-361. By their conduct as pleaded, Defendant as suppliers in this consumer transaction violated provisions of that law.

226. The goods manufactured and supplied by Defendant was defective in construction or composition in that, when they left the hands of Defendant, they deviated in a material way from defendant's manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. In particular, the product is not safe for use by pregnant women, has numerous and serious side effects and causes severe and permanent injuries. These goods were unreasonably dangerous under New York law.

227. The subject product manufactured and supplied by Defendant was defective in design in that, an alternative design exists that would prevent serious side effects and severe and permanent injury to pregnant women and their unborn children. The product was unreasonably dangerous in design under Virginia Law.

228. The subject product manufactured and supplied by Defendant was unreasonably dangerous because they did not provide an adequate warning about the use of ondansetron by pregnant women. At the time the subject product left Defendant's control, it possessed a characteristic that may cause damage to pregnant women and their unborn children, and Defendant failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product. The product is not safe, has numerous and serious side effects, and causes severe and permanent injuries. The product was unreasonably dangerous because of inadequate warning under New York Law.

229. The subject goods manufactured and supplied by Defendant was unreasonably dangerous because it did not conform to an express warranty made by Defendant regarding the product's safety and fitness for use. Defendant expressly warranted that ondansetron was safe for use by pregnant women to treat pregnancy-related nausea induced Plaintiff to use the product, and Plaintiff's damages were proximately caused because Defendant's express warranty was untrue. The product was unreasonably dangerous because of nonconformity to express warranty under New York law.

230. Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

231. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law §§ 354 - 361 and other similar statutes.

232. The State of New York and all other states and the District of Columbia have enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when Defendants knew it was defective and dangerous, and by other acts alleged herein.

233. Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff.

234. As a direct and proximate result of Defendants' violations of New York General Business Law §§ 354 - 361. and other various consumer protection statutes enacted in other states and the District of Columbia, Plaintiff has suffered damages, for which Plaintiff is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

235. By reason of the foregoing, Plaintiffs demand judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.


PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demands judgment against GSK on each of the above-referenced claims and Causes of Action and as follows:

- a. For general damages in a sum in excess of the jurisdictional minimum of this Court;
- b. For medical, incidental and hospital expenses according to proof;
- c. For pre-judgment and post-judgment interest as provided by law;
- d. For consequential damages in excess of the jurisdictional minimum of this Court;
- e. For compensatory damages in excess of the jurisdictional minimum of this Court;
- f. For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;
- g. For attorneys' fees, expenses and costs of this action; and
- h. For such further and other relief as this Court deems necessary, just and proper.

Dated: April 11, 2019

ARNOLD E. DIJOSEPH, PC.

By  _____

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Index No.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

LESLIE COSOLITO, on behalf of
A.C., her minor child,

Plaintiffs,

-against-

GLAXOSMITHKLINE, LLC

Defendant.

CIVIL COVER SHEET, COMPLAINT AND JURY DEMAND

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